

REMARKS

Claims 124-134 are pending in this application. Claims 128-134 are withdrawn by the examiner. Claims 124, 125 and 127 are amended for clarity and the amendments are supported by the specification as discussed herein. Therefore, no new matter is introduced. The office action is discussed below:

Rejection Withdrawn:

Applicants thank the examiner for withdrawal of the anticipation rejection of claims 124-127 and Salovey *et al.* (6,281,264, having an effective filing date of January 20, 1995) as an anticipatory art in view of the response filed on July 27, 2007.

Response to the Arguments and Rejections Maintained by the Examiner:

Written Description Rejection:

On pages 2-4 and 5-6 of the Office Action, the examiner has maintained the alleged rejection of claims 124-127 for various written description-related reasons.

On page 2 of the Office Action, the examiner opines that the instant claim language is not supported by the disclosures of 08/600,744 or 08/726,313 and thus not entitled to the earlier priority dates thereof. Applicants respectfully disagree with the examiner and traverse the rejection for the reasons discussed herein.

On pages 2-3 of the Office Action, with respect to the specification support that applicants submitted regarding heating at or above its melting temperature for about 5 minutes to about 3 hours and for heating to about 175°C (below the decomposition temperature of the polyethylene), the examiner asserts that the claims recite "polyethylene", not UHMWPE. Thus, according to the examiner, the temperature less than the decomposition temperature of the polyethylene in the method set forth can be a temperature less than the decomposition temperature of numerous alternative samples of polyethylene, including UHMWPE. Applicants disagree with the examiner

and refer to Saum *et al.* (see for example, Saum, *et al.* US 6,562,540, col. 6, lines 34-41, that discloses UHMWPE is pre-annealed to a temperature of 280°C to 355°C, preferably 320°C to 355°C, without reaching its decomposition temperature) that claims pre-annealing below the decomposition temperature of the polyethylene based on the above disclosure which refers to UHMWPE. Applicants also refer that the Saum *et al.* disclosure relates to UHMWPE (see for example, col. 1, lines 20-24, the field of invention), hence, the decomposition temperature of the polyethylene referred therein applies to UHMWPE aspect of the disclosure. However, in order to expedite the prosecution, applicants amend the claims 124, 125 and 127 to replace the term "polyethylene" with the term "UHMWPE."

On pages 2-3 and 5 of the Office Action, the examiner asserts, the specification as filed, does not mention "pre-annealing" or the temperatures for "pre-annealing." According to the examiner, the "pre-heating to a temperature below the melting temperature of the UHMWPE" in the WIR-SM or WIR-AM method is disclosed. The examiner interprets that the disclosed MIR method teaches melting the UHMWPE, which is not considered by the examiner to be equivalent to "pre-annealing", as set forth in the instant claims, or to "preheating", as disclosed in the WIR methods in the instant specification. Applicants disagree with the examiner and submit that the term "pre-heating" is generally regarded as "pre-annealing" in the art, see for example, the Saum '540 patent, col. 6, lines 34-41, wherein the UHMWPE was subjected to "pre-annealing", i.e., subjected to "pre-heating" to a temperature of 280°C-355°C, which are temperatures above the melting point of the UHMWPE. Applicants also refer to the instant specification for example, Example 3, at page 41, that the temperature varied "between 200°C at the base to 175°C at the top.... [and] was held at these temperatures for a period of 30 minutes before starting the irradiation." The heating was continued until "[a]fter irradiation, the heating was stopped and the cup was allowed to cool to room temperature." The specification, thus clearly discloses "pre-annealing" for a period of time "greater than 30 minutes", because the heating continued until after irradiation and then cool slowly (which satisfies examiner's

asserted definition of “annealing” or “pre-annealing” (see page 2 of the Office Action of September 28, 2006). Therefore, the specification has full support for the claim recitation of the term “pre-annealing.”

With respect to the recitation a “period of time greater than 30 minutes”, the Examiner has found no recognition in the specification that greater than 30 minutes is a significant time period combined with pre-annealing or pre-heating. The examiner interprets that the disclosure on page 30 of a time period of about 30 minutes to about 2 hours is a description of the time period for maintaining the UHMWPE above the melting temperature before irradiation in the MIR embodiment. Applicants believe that the examiner has failed to understand the specification on page 30 and indicate that the specification (see page 30, lines 8-12) clearly describes that “the heating is maintained so to keep the polymer at the preferred temperature for about 5 minutes to about 3 hours, and more preferably for about 30 minutes to about 2 hours. The UHMWPE is then irradiated with gamma irradiation or electron irradiation.” Therefore, it is clear that the “heating” or “pre-heating” or “pre-annealing” of the UHMWPE was maintained for a “period of time greater than 30 minutes” prior to irradiation.

The examiner also interprets that the description of cooling slowly in the MIR process is a process step following irradiation and not a disclosure of “pre-annealing”. Applicants disagree with the examiner and point out that the examiner also has failed to understand the specification and the clarification provided in response to previous Office Action.

Applicants further clarify that “cooling slowly” is a step after the “quenching” step as recited in claim 125. Applicants remind the examiner that claim 125 does not recite a slow cooling step as a disclosure of “pre-annealing”, as noted by the examiner on page 3 of the Office Action. Therefore, the issue raised by the examiner regarding “pre-annealing” and “cooling slowly” is irrelevant to the claimed invention.

Thus, the specification clearly discloses “pre-annealing” for a period of time “greater than 30 minutes”, because the heating continued until after irradiation and then cool slowly (which satisfies examiner’s asserted definition of “annealing” or “pre-

annealing”, see above and page 2 of the Office Action of September 28, 2006). Therefore, the specification has full support for the claim recitation of “pre-annealing a polyethylene preform at a temperature greater than ambient temperature and less than the decomposition temperature of the polyethylene for a period of time greater than 30 minutes.”

On page 4 of the Office Action, the examiner asserts that no time period for heating has been noted for the disclosed WIR processes that include “pre-heating.” Again, applicants disagree with the examiner and refer to the specification, for example, Example 10 at page 49, which clearly discloses a time period such as “overnight” (which is greater than 30 minutes) pre-heating prior to the irradiation step.

Withdrawal of the written description rejection is therefore solicited.

Anticipation/Obviousness Rejections:

On pages 4 and 7-8 of the Office Action, the examiner has maintained the alleged anticipation and obviousness rejections of claims 124-127 in view of Shalaby (the ‘411 patent) and Sun (the ‘049 patent), respectively, of the record.

On page 7 of the Office Action, the examiner reiterates that Shalaby *et al.* disclose a method that comprises melting an UHMWPE “construct polymer-fiber” and irradiating the resulting composite with high energy radiation to sterilize and crosslink composites of the UHMWPE (refers to column 2, lines 11-27, column 3, lines 9-18, column 5, line 32, to column 6, line 10, and Examples 1 and 5). Applicants respectfully disagree with the examiner and submit that Shalaby discloses the melting of ultrahigh molecular weight polyethylene (UHMWPE) powder for consolidation followed by the production of UHMWPE fibers to reinforce UHMWPE composites. It is clearly noted in the ‘411 patent that the “polymer-fiber construct” is made after melting the UHMWPE powder to reduce its melting point so that the fibers do not melt. That is, the “UHMWPE powder cannot be used directly in making composites because its melting point temperature is very close to that of the fiber so that fibers might also melt” (see

the '411 patent, Example 1, col. 6, lines 54-57). Therefore, Shalaby does not disclose a method of making an UHMWPE "construct polymer-fiber" by melting or pre-heating or pre-annealing the UHMWPE "construct polymer-fiber."

With respect to the instant claim recitation of the phrase "irradiating the polyethylene perform, thereby crosslinking the polyethylene preform", the examiner states that Shalaby or Sun's "low dose irradiation" or "sterilization irradiation" is encompassed by the instantly claimed phrase. According to the examiner, the irradiation as taught by Shalaby or Sun would be expected to crosslink the polyethylene and thus meet the requirements of the phrase "thereby crosslinking the polyethylene preform." The examiner states, Shalaby teaches that high energy radiation crosslinks the UHMWPE (refers to column 6, lines 1-7). The examiner also states that the crosslinking would be an expected result of the prior art irradiation since the prior art teaches the irradiation of a polyethylene preform. The examiner also states that the instant claims do not place any limitations on irradiation conditions, such as dose, rate or time, that might distinguish over sterilizing radiation.

Applicants disagree with the examiner and point out that the "low dose irradiation" or "sterilization irradiation" of Shalaby or Sun would generate residual free radicals and would not be "quenching residual free radicals in the ultrahigh molecular weight polyethylene preform subsequent to the irradiating step", as required by the claimed method. Therefore, Shalaby and/or Sun does not disclose the claimed method. In this context, applicants refer the examiner to MPEP that:

"The Patent and Trademark Office ("PTO") determines the scope of claims in patent applications not solely on the basis of the claim language, but upon giving claims their broadest reasonable construction "in light of the specification as it would be interpreted by one of ordinary skill in the art." *In re Am. Acad. of Sci. Tech. Ctr.*, 367 F.3d 1359, 1364[, 70 USPQ2d 1827] (Fed. Cir. 2004)."

See MPEP 2111 at 2100-37 (Rev. 5, August 2006).

Accordingly, Shalaby or Sun's "low dose irradiation" or "sterilization irradiation" does not encompass the recited claim phrase.

Applicants point out that Shalaby describes that the consolidated UHMWPE can be irradiated for sterilization (see column 6, lines 3-5, also see columns 2 and 4). Applicants also point out that Shalaby's UHMWPE "construct polymer fiber" is irradiated at 2.5 Mrads for sterilization using gamma radiation, meaning that a finished product is irradiated at room temperature and is not later melted to allow free radicals to recombine.

Moreover, it is specifically noted in the '411 patent that the melting of the UHMWPE (when it is in a powder form) component of the final product was to avoid melting of the fibers of the product. Hence, a heating or melting to allow free radicals to recombine in the final product is not taught in the '411 patent, because, the final product made by Shalaby were not processed to recombine the free radicals in the final product by quenching or any other methods. Thus, Shalaby *et al.* does not allow recombination of free radicals. Accordingly, Shalaby's finished product will possess free radicals, and thus be susceptible to oxidation, as Shalaby disclosed in column 4, lines 56-58. Therefore, Shalaby (the '411 patent) process cannot yield a product made by any of the claimed processes.

Finally, applicants refer to above discussion and submit that the "low dose irradiation" or "sterilization irradiation" of Shalaby or Sun would generate residual free radicals and would not be quenching residual free radicals in the ultrahigh molecular weight polyethylene preform subsequent to the irradiating step, as required by the claimed method. Therefore, Shalaby and/or Sun does not anticipate the claimed methods nor make the claimed methods obvious. Accordingly, withdrawal of the anticipation/obviousness rejections is requested.

Double Patenting Rejection:

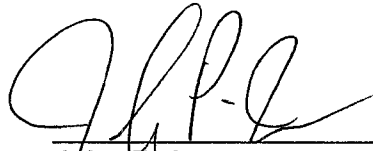
On pages 4 and 8-10 of the Office Action, the examiner also has maintained the provisional rejection of claims 124-127 under the judicially created doctrine of obviousness-type double patenting and alleged as being unpatentable over pending claims of co-pending applications serial nos. 10/948,440, 10/197,209, 10/696,362, 10/901,089 and 10/197,263.

Applicants remind the examiner that none of the cited co-pending applications have received a notice of allowance, the merits of this provisional rejection need not be discussed at this time. See MPEP § 822.01.

REQUEST

Applicants submit that claims 124-127 are in condition for allowance, and respectfully request favorable consideration to that effect. The examiner is invited to contact the undersigned at (202) 416-6800 should there be any questions.

Respectfully submitted,



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Date

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